

REMARKS

Claims 1, 9, 10, 43, and 73-117 are pending in the application. Claims 2-8, 11-42, and 44-72 have been cancelled without prejudice by the present response. Claims 1, 9, and 10 have been amended. New claims 73-117 have been added. Support for the amendments and new claims can be found in the original claims and in the specification at, e.g., page 11, lines 24-26; page 17, line 16, to page 20, line 8; page 20, line 26, to page 21, line 6; page 27, line 19, to page 31, line 18; and page 34, line 11, to page 35, line 29. No new matter has been added.

35 U.S.C. §112, Second Paragraph

At pages 2-3 of the Office Action, claims 1, 9, 10, 16, 17, 20-22, and 43 were rejected as allegedly incomplete for omitting essential elements. According to the Office Action, the omitted elements are “the intended nucleotide sequence that comprising [sic] an epitope of a naturally occurring human papillomavirus protein.”

Independent claim 1 has been amended to recite specific amino acid sequences derived from human papillomavirus proteins. It is applicants' understanding that the recitation of human papilloma virus sequences obviates the rejection of independent claim 1 and the claims that depend therefrom.

35 U.S.C. §102(b)

At pages 3-4 of the Office Action, claims 1, 9, 10, 16, 17, 20-22, and 43 were rejected as allegedly anticipated by Edwards et al., U.S. Patent No. 6,306,397 (“Edwards”). Applicants respectfully traverse the rejection in view of the claim amendments and the following remarks.

As detailed in the specification, the inventors have made the surprising discovery that the nucleic acid construct designated “ZYC101a” is particularly effective in treating cervical intraepithelial neoplasia (CIN) in human subjects of specific ages. Consistent with those experimental findings, independent claim 1 has been amended to require that (i) the human subject treated according to the claimed method be identified as being less than 25 years of age, and (ii) the nucleic acid used in the claimed method contain a nucleotide sequence that encodes a

hybrid polypeptide that contains at least four of the segments that are present in ZYC101a (with the at least four segments being derived from each of four different human papilloma virus proteins, HPV16 E6, HPV16 E7, HPV18 E6, and HPV18 E7).

Edwards describes variants of human papilloma virus antigens for use in vaccines. Edwards does not describe the treatment of a human subject that has a CIN and has been identified as being less than 25 years of age, as is required by the claims. For that reason alone, Edwards does not anticipate the claimed methods.

The Office Action stated that "Applicants are reminded that [the] limitation of 30 years of age and younger has no patentable weight, because Edwards et al broadly taught inducing immune response in a human host which comprises the intended age limit." Applicants contest the assertion that Edwards inherently discloses treatment of a CIN in a human subject identified as being less than 25 years of age. Edwards contains no indication that CIN subjects within any particular age group, much less the age group recited in the claims, are particularly suitable to treatment with the compositions described therein. Edwards' description of treatment of the genus of "patients" does not constitute a disclosure of the species of treatment of the particular subset of human subjects having a CIN that the inventors have surprisingly found to be particularly amenable to treatment with the ZYC101a composition.

In view of the foregoing comments, applicants respectfully submit that Edwards does not anticipate the claims and request that the Examiner withdraw the rejection.

35 U.S.C. §102(e)

At pages 4-6 of the Office Action, claims 1, 9, 10, 16, 17, 20-22, and 43 were rejected as allegedly anticipated by each of Ertl et al., U.S. Patent No. 7,132,262 ("Ertl") and Webb et al., U.S. Patent No. 6,726,912 ("Webb"). Applicants respectfully traverse the rejections in view of the claim amendments and the following remarks.

As noted above, the amended claims reflect the inventors' surprising discovery that the nucleic acid construct ZYC101a is particularly effective in treating CIN in human subjects of specific ages.

Ertl describes human papilloma virus antigen-encoding polynucleotides having particular codon usage patterns for the treatment and prevention of human papilloma virus infections. Webb describes polyprotein constructs useful for eliciting an immune response against a human papilloma virus in a host.

Neither Ertl nor Webb describes the treatment of a human subject that has a CIN and has been identified as being less than 25 years of age, as is required by the claims. For that reason alone, the references do not anticipate the claimed methods.

The Office Action asserted that each of Ertl and Webb inherently anticipate the claims, using essentially identical language in each of the rejections as was used in the Edwards anticipation rejection. Similar to the comments above in response to the Edwards rejection, Applicants contest the assertion that Ertl and Webb inherently disclose treatment of a CIN in a human subject identified as being less than 25 years of age. Ertl and Webb contain no indication that CIN subjects within any particular age group, much less the age group recited in the claims, are particularly suitable to treatment with the compositions described in the references. The description in Ertl and Webb of treatment of the genus of "patients" or "subjects" does not constitute a disclosure of the species of treatment of the particular subset of human subjects having a CIN that the inventors have surprisingly found to be particularly amenable to treatment with the ZYC101a composition.

In view of the foregoing comments, applicants respectfully submit that Ertl and Webb do not anticipate the claims and request that the Examiner withdraw the rejection.

CONCLUSIONS

Applicants submit that all grounds for rejection have been overcome, and that all claims are now in condition for allowance.

Enclosed is a Petition for Three-Month Extension of Time. The extension of time fee is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 08191-029US1.

Respectfully submitted,

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